RISK CHARACTERIZATION

Introduction

The purpose of this analysis is to characterize the risk from the land application of sewage sludge to farm land in the terms of EPA's Guidelines for Exposure Assessment (the "Guidelines") which is the Agency's primary guidance for characterizing risk to exposed populations from pollutants.

EPA set out to perform a "high end' exposure evaluation/risk assessment as the technical basis for the development of a numerical standard for the application of sewage sludge to agricultural land. This analysis enumerates and characterizes the key portions of our risk assessment to be able to compare them to the principles in the Guidelines and describes a risk characterization.

The Part 503 Standards for the Use or Disposal of Sewage Sludge establishes numerical standards for pollutants in sewage sludge to protect the public from adverse health impacts from the presence of these pollutants. The Part 503 standards apply to three common sewage sludge management practices: land application to a variety of terrestrial environments, surface disposal (burial or isolation), and incineration. The subject of the risk assessment and its characterization is focused on the most critical practice (with respect to exposure and subsequent risk to highly exposed individuals), the application of sewage sludge containing dioxins to farm land.

There is agreement that most of the general population's exposure to dioxins results from the consumption of animal products in the diet where dioxin is concentrated in the lipid portion of the meats and dairy products. The Part 503 Standards are developed by modeling highly exposed ("high end") populations to establish numerical standards that protect these populations from exposure to the pollutant of concern. We chose the farm family as the "high end" exposed population to be modeled since a key assumption is that their diets have significantly greater percentages of meat and dairy products from their own farms where sewage sludge is land applied as a fertilizer or soil amendment. Members of this farm family are, therefore, at greatest risk from exposure to dioxins because of their life style, most importantly their dietary habits. While the risk assessment that we performed is on a "high end" exposed population and not on the general population, one can draw conclusions on the protectiveness of the risk assessment for the general population. By establishing numerical standards to protect this "high end" modeled population from exposure to dioxins, the general population is also protected from the same pathways of exposure with a greater margin of safety since the diet of the general population contains only a small fraction of meat products grown on farms with land applied sewage sludge.

This analysis characterizes three components of the risk assessment:

- The exposure scenario
- Key assumptions and data used in the exposure assessment modeling
- The cancer/slope factor (Q1*)

Each of these components is then compared to the relevant portions of the Guidelines to characterize them as either “high end” or “central tendency”. Finally, a characterization of the risk to the modeled population is stated along with its rationale based on the principles of the Guidelines.

Description of the Sewage Sludge Practice Being Modeled

Sewage sludge is land applied to farms for the purpose of providing nutrients to crops being grown or amending the soil to enhance agronomic properties such as tilth. Sewage sludge containing dioxins is applied periodically and continuously on this farm where a farm family resides. Included in this family are toddlers and nursing infants**.**

Description of the Exposure Scenario for the Land Application of Sewage Sludge and the Population Modeled

Sewage sludge is assumed to be applied at agronomic rates to agricultural land. It is further assumed that the amended agricultural land used for the production of vegetables, fruits, and root crops is tilled and that the pasturage to which sewage sludge is applied is not tilled. Each time that the sewage sludge is applied to the pasture, it is assumed to remain in the top 2 cm. of the land surface and not diluted with the receiving soil. This allows for maximum dioxin in sewage sludge-to plant volatilization transport to occur. In addition, this pasturing scenario is never varied; the farmer never rotates the pasture to grow row crops where presumably, tilling of sewage sludge in the soil would occur to mitigate dioxin volatization transport to the row crops. The farm modeled is assumed to be the median size for each region of the country that is modeled. Thus, the farm size is not constant throughout the analysis, but reflects the regional variation in agricultural practices. The farm is assumed to devote half of its area to crop production (tilled) and half of its area to raising animals (untilled pasture land). The application rates and frequency of application of sewage sludge are estimated separately for each type of land use and are presented as distributions.

The farm family that lives immediately adjacent to the field may be exposed to any single agricultural product (cattle and/or crop) or combination of agricultural products produced on the farm. The farm family also is assumed to raise free-range chickens near its house (in the buffer area). On the opposite side of the house from the field and pasture is a fishable stream where a resident fisher is assumed to catch fish for personal consumption. For the purpose of the exposure assessment and risk assessment, all pathways of exposure to dioxins are summed.

The above-described scenario is characterized as a "high end" dioxin-exposure population. Approximately 95 percent of an individual's daily dioxin exposure in the general population is the result of animal products in the diet. The modeled population consumes a significantly higher fraction of home raised crops and animal products contaminated with dioxins from the sewage sludge that is land applied to the farm compared to the general population.

Key Assumptions and Data Used to Model the Population in the Exposure Scenario

Why are these key assumptions and data being enumerated and characterized?

The following paragraphs are taken from EPA's Guidelines for Exposure Assessment, EPA/600Z-92-001. 57 Fed.Reg. 22888-22938.

"The high end risk is a plausible estimate of individual risk for those persons at the upper end of the risk distribution. The intent of this descriptor is to convey an estimate of risk in the upper range of the distribution, but to avoid estimates that are beyond the true distribution. Conceptually, high end risk means risks above the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest risk. This descriptor is intended to estimate the risks that are expected to occur in small but definable high end segments of the subject population. The use of "above the 90th percentile" in the definition is not meant to precisely define the range of this descriptor, but rather to clarify what is meant conceptually by high end."

"If some information on the distribution of the variables making up the exposure to dose equation (e.g., environmental concentrations, exposure duration, intake, or uptake rates) is available, the risk assessor may estimate a value which falls into the high end by meeting the defining criteria of "high end": an estimate that will be within the distribution, but high enough so that less than 1 out of 10 in the distribution will be as high. **The risk assessor often constructs such an estimate by using maximum or near maximum values for one or more of the most sensitive variables, leaving others at their mean values.** (Emphasis added). The exact method used to calculate the estimate of high end exposure or dose is not critical; it is important that the exposure assessor explain why the estimate, in his or her opinion, falls into the appropriate range, no above or below it."

Therefore, this risk characterization depends upon the enumeration and characterization of these key assumptions and data for comparison to the above-quoted paragraphs from the EPA Guidelines for Exposure Assessment.

Most of the parameters used in the Monte Carlo simulations are distribution of values for each parameter. The following are some of the fixed parameters used in the Monte Carlo simulations and their characterizations: High end characterizations are in bold faced type.

• **Exposure Frequency- 350 days/year. This is characterized as high end.**

• **Fraction of diet for home-caught fish- 100%. This is characterized as high end.**

• Fractions of home produced beef, milk, eggs, and poultry- various values taken from EPA's 1997 Exposure Factors Handbook for the farm population modeled in this scenario. These values are mean or central tendency for this highly exposed farm population ("the scenario").

• **Fraction of soil ingested that is contaminated- 100%. This is characterized as high end.**

• Fractions of home produced exposed fruit, exposed vegetables, root vegetables for the farmer, and exposed fruit, exposed vegetables and root vegetables for the home gardener- various values taken from EPA's Exposure Factors Handbook for the populations modeled in these scenarios. These values are mean or central tendency.

• Fraction of food preparation loss for exposed fruit, exposed vegetables, and root vegetables- various values taken from EPA's Exposure Factors Handbook and are mean or central tendency.

• Percent cooking and percent post-cooking loss for beef and poultry- various values taken from EPA's Exposure Factors Handbook. These values are mean or central tendency.

• Fraction of home-caught fish that are at trophic levels 3 and 4 (high dioxin bio-accumulating fish)- various values taken from EPA's Exposure Factors Handbook. These values are mean or central tendency.

• Soil ingestion rates for children and adults- various values taken from EPA's Exposure Factors Handbook. These values are mean or central tendency.

• Biological half life of dioxin in lactating women- literature value

• Concentration of dioxin in aqueous phase of maternal milk- literature value

• Fraction of fat in maternal breast milk- literature value

• Fraction of ingested dioxin absorbed by the infant- literature value

- **Fraction of ingested dioxin absorbed by the mother- 100 % high end value**

- Fraction of mother's weight that is fat- literature value

- Proportion of dioxin stored in maternal fat- literature value

A parameter with a distribution function in the multi-pathway exposure analysis and risk assessment are the concentrations of dioxins in the sewage sludge that is land applied. Distribution of dioxin concentrations in sewage sludge came from analysis of sewage sludge samples from randomly selected POTWs across the United States. The 2001 National Sewage Sludge Survey was designed to produce an unbiased estimate of dioxin and dioxin-like compounds in sewage sludge. As such, the results from this Survey represent up to date information on the concentrations of dioxins in the Nation's sewage sludge. The Survey employed state of the art analytical methodologies that yielded very low analytical detection limits for each of the 29 congeners surveyed.

Cancer Dose Response Slope

• The cancer slope (dose-response) or Q1* $1.56 \times 10^{+5}$ (mg./kg./day)$^{-1}$. This value is characterized as the upper bound (at the 95th percentile confidence level) on the slope of the dose-response curve in the low-dose region and is generally assumed to be linear. As such, this key value is characterized as high end. Note: The Q1* in EPA's Draft Dioxin Reassessment has a value 6 times that of the current Q1*. The above-described high end characterization applies to this value as well.

Monte Carlo Dioxins in Sewage Sludge Exposure To Dose Simulations for the Above-Described Scenario

Monte Carlo (Stochastic/Probabilistic) exposure to dose simulation for dioxins were performed with the fixed value parameters listed above and several distributional parameters. Exposure to dose outputs were converted to incremental cancer risks for the modeled population as defined in the above-characterized scenario.

A risk management decision was made to express the incremental cancer risk to the population modeled in the scenario at the 50th percentile. This decision was made based on EPA's characterization of these risk simulations as "high end" as described below.

Analysis and Conclusion- Statement of the Characterization of Risk and Rationale

We characterize the risk assessment as "high end" within this modeled population based on the following with reference and consideration of the above-cited sections abstracted from EPA's Guidelines for Exposure Assessment: The analysis has defined the exposure scenario for the modeled population as "high end".

• Five of the key fixed parameters in the exposure to dose assessment are characterized as "high end" as described earlier in this paper. They are: the cancer slope (Q1*), exposure frequency, fraction of diet for home-caught fish, fraction of soil ingested that is contaminated, and fraction of ingested dioxin absorbed by the nursing mother.

• All other values used in the exposure to dose assessment are either central tendency (mean) values or are distribution of values used in the Monte Carlo simulations.

• The other scenario factors of the assumption that sewage sludge always resides in the top 2 cm. of the agricultural land surface, pasturing is employed continuously with no crop rotation, and all exposure pathways for the modeled population are summed as described previously reinforce the characterization of this exposure to dose assessment as "high end". It may also be acceptable to characterize this risk assessment as the "high end" of the "high end".